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ATTY DOCKET NO. 47-00B	SERIAL NO. 10/616/692	FILING DATE July 9, 2003
APPLICANT J. Nelson		GROUP 1614

## **U.S. PATENT DOCUMENTS**

Exmr. Initial	Document Number	Date	Name	Class	Subclas s	Filing Date if Appropriate
Na	6,232,326	05/15/01	Nelson	514	336	
	5, 430,039	07/04/95	Roberts-Lewis et al.	514	297	

# **FOREIGN PATENT DOCUMENTS**

	Document Number	Date	Country	Class	Subclas s	Translation Yes/No

OTHER PRIOR ART (including Author, Title, Date, Pertinent Pages, etc.)

	OTHER PRIOR ART (including Author, Title, Date, Pertinent Pages, etc.)
M	Aisen, P.S., "Multicenter trial of hydroxychloroquine," CRISP (1998) abstract only
M	Allison, J. L., O'Brien, R. L. and Hahn, F. E., (1965), "Nature of thedeoxyribonucleic acid-chloroquine complex," <i>Antimicrob Agents Chemother</i> , 5:310-314
W.	Amabeoku, G. J. and Chikuni, O. (1992), "Involvement of GABAnergic mechanisms in chloroquine-induced seizures in mice," <i>Gen Pharma</i> , 23(2):225-229
W.	Amabeoku, G. J. (1994), "Some behavioral effects of chloroquine in rats suggesting dopaminergic activation," <i>Indian J Med Res</i> , 99: 87-94
W	Amabeoku, G. J. and Chikuni, O. (1992), "Chloroquine-induced seizures in mice: the role of dopaminergic system," <i>Br. J Pharmacol</i> , 106: 54P, abstract only
THIS .	Amabeoku, G. J. and Chikuni, O. (1992), "Chloroquine-induced seizures in mice: the role of monoaminergic mechanisms," Eur J Neuropsychopharm, 3: 37-44
Chi.	Augustijns, P. and Verbeke, N. (1992), "Stereoselectivity in the disposition of chloroquine and desethyl-chloroquine in rabbits," <i>Arzneimittelforschung</i> , 42(6):825-828
	Augustijns, P., Geusens, P. and Verbeke, N. (1992), "Chloroquine levels in blood during chronic treatment of patients with rheumatoid arthritis," <i>Eur J Clin Pharmacol</i> , 42:429-433
W	Batchelor, P. E. et al. (1999), "Activated macrophages and microglia induced dopaminergic sprouting in the injured striatum and express brain derived
19	neurotrophic factor and glial cell line derived neutrophic factor, " J Neurosci, 19(5):1708-1716

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Form PTO 1449		
ATTY DOCKET NO. 47-00B	SERIAL NO. 10/616/692	FILING DATE July 9, 2003
APPLICANT J. Nelson		GROUP 1614

N.	Batchelor, P. E. et al. (1999), "Activated macrophages and microglia induced dopaminergic sprouting in the injured striatum and express brain derived neurotrophic factor and glial cell line derived neutrophic factor," <i>J Neurosci</i> , 19(5):1708-1716
	Ben-Shachar, D. et al. (1995), "Dopamine neurotoxicity inhibition of mitochondrial respiration," <i>J Neurochem</i> , 64:718-723
W	Bergmann, K. J., et al. (1986), "Parkinson's disease and long term levodopa therapy," Adv Neurol, 45:463-467
	Bhakar, A. L., et al. (2002), "Constitutive nuclear factor kappa B activity is required for central neuron survival," <i>J Neurosci</i> , 22(19):8466-8475
	Bodnar, R. J., et al. (1990), "Proglumide selectively potentiates supraspinal mu 1 opioid analgesia in mice," <i>Neuropharmacol</i> , 29(5):507-510
	Brockmoller, J., et al. (2002), "The importance of the CYP2D6 polymorphism on haloperidol pharmacokinetics and on the outcome of haloperidol treatment," Clin Pharmacol & Therap, 72(4):438-452
847	Brooks, D. J. and Samuel, M. (2000), "The effects of surgical treatment of parkinson's disease and tremor: articles" <i>Am Acad Neurol</i> , 55(12):S52-S59
W	Brooks, D. J., et al. (2000), "Neuroimaging of dyskinesia," <i>Ann Neurol</i> , 47(suppl 1):S154-S159
W	Buszman, E., et al. (1984), "Electron spin resonance studies of chloroquine-melanin complexes," <i>Biochem Pharmacol</i> , 33(1):7-11
M	Cadet, J. L. and Kahler, L. A. (1989), "Free radical mechanisms in schizophrenia and tardive dyskinesia," <i>Neurosci Behav Rev</i> , 18(4):457-467
A	Carta, A., et al. (2002), "Differential regulation of GAD67, enkephalin and dynorphin mRNA by chronic-intermittent I-dopa and A <sub>2a</sub> receptor blockade plus I-dopa in dopamine-denervated rats," Synapse, 44:166-174
	Chang, K. J., et al. (1982), "Opioid peptides induce reduction of enkephalin receptors in cultured neuroblastoma cells," <i>Nature</i> , 296:446-448
	Chase, T. N. et al. (1986), "Fluctuation in response to chronic levodopa therapy pathogenetic and therapeutic considerations," <i>Adv Neurol</i> , 45:477-480
W	Chen, F. Lu et al. (1997), "Calpain contributes to silica induced I kappa B-alpha degradation and nuclear factor-kappa B activation," <i>Arch Biochem Biophysics</i> , 342(2):383-388
+	Chen, F. Lu et al. (1997), "Calpain contributes to silica induced I kappa B-alpha degradation and nuclear factor-kappa B-activation," Arch Biochem Biophysics, 342(2):383-388
	Cheng, N. et al. (1996), "Differential neurotoxicity induced by I-dopa and dopamine in cultured striatal neurons," <i>Brain Res</i> , 743(1-2):278-283
	Chiodo, L. A. and Bunney B. S. (1983), "Typical and atypical neuroleptics: differential effects of chronic administration on the activity of A9 and A10 midbrain dopaminergic neurons," <i>J Neurosci</i> , 3(8):1607-1619
	Chugani, D. C. et al. (1988), "In vivo [ <sup>3</sup> H]spiperone binding: evidence for accumulation in corpus striatum by agonist-mediated receptor internalization," <i>J Cereb Blood Flow &amp; Metab</i> , 8(3):291-303
	Cohen, S. N. and Yielding, K. L., (1965), "Inhibition of DNA and RNA polymerase reactions by chloroquine," <i>Proc Natl Acad Sci</i> , 54(2):521-527.

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Form PTO 1449		
ATTY DOCKET NO. 47-00B	SERIAL NO. 10/616/692	FILING DATE July 9, 2003
APPLICANT J. Nelson		GROUP 1614

	Coleman, T. et al., "1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine (MPTP) is n-
	demethylated by cytochromes P450 2D6, 1A2 and 3A4 –Implications for
	susceptibility to Parkinson's Disease," <i>J. Pharm. And Exp. Therapeutics</i> , 277(2):685-690
	Conley, R. R., and Buchanan, R. W. (1997), "Evaluation of treatment resistant
	schizophrenia," Schizo Bull, 23(4):663-674
17	Cooper, A. and Mitchell, I. (1995), "Fos immuno-positive neurons in the STN
	following reversal of Parkinson's disease symptoms by antagonism of excitatory
	amino acid transmission in the entopeduncular nucleus of the monoamine
	depleted rat," Neurosci Let, 201(3):251-254
W	Dahl, M-L, "Cytochrome P450 phenotyping/genotyping in patients receiving
	antipsychotics: useful aid to prescribing," Clin Pharmacokinet, 41(7):453-470  D'Amato, R. J. et al. (1987), "Characterization of the binding of N-methyl-4-
	phenylpyridine, the toxic metabolite of the parkinsonian neurotoxin N-methyl-4-
	phenyl-1,2,3,6-tetrahydropyridine to neuromelanin," <i>J Neurochem</i> , 48(2):653-658
	Davis, G.C. et al. (1979), "Chronic parkinsonism secondary to intravenous
18/	injection of meperidine analogues," Psych Res, 1:249-254
	Deutch, A. Y. (1993), "Prefrontal cortical dopamine systems and the elaboration
	of functional corticostriatal circuits: implications for schizophrenia and parkinson's
H(-4\	disease," J Neural Trans, 91(2-3):197-221
\dd\   .	Doss, R. C. et al. (1981), "Recovery of β-adrenergic receptors following long term
	exposure of astrocytoma cells to catecholamine," <i>J Biol Chem</i> , 258:12281-12286  Egan, M. F. et al. (1997), "Treatment of tardive dyskinesia," <i>Schizo Bull</i> ,
100	23(4):583-609
N	Egan, M. F. et al.(1996), "Pharmacological and neurochemical differences
	between acute and tardive viscous chewing movements induced by haloperidol,"
	Psychopharmacol, 127:337-345  Elbert, M.H et al. (1984), "Selective neurotoxic effects of n-methyl-4-phenyl-
	1,2,3,6-tetrahydropyridine (MPTP) in subhuman primates and man: a new animal
	model of parkinson's disease," Psychopharmacol Bull, 20(3):548-553
	Essien, E. E. and Ette, E. I., (1986), "Effects of chloroquine and
	didesethylchloroquine on rabbit myocardium and mitochondria," J Pharm
	Pharmacol, (38):543-546
	Essien, E. E. et al. (1989), "Chloroquine disposition in hypersensitive subjects
\W\ \	and its significance in chloroquine-induced pruritus," Eur J of Drug Metab and Pharmacokinet, 14(1):71-77
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Ette, E. I. and Essien, E. E. (1986), "Neuromuscular weakness and
	ultrastructural damage produced by desethylated metabolites of chloroquine and
	the reversal by calcium," West African J of Anatomy 1(1):5-15
XU	Feigenbaum, P. E. and Fakahny, E. E. (1984), "Short term regulation of
	muscarinic acetylcholine receptor grinding in cultured nerve cells," Res Commum
<del></del>	Chem Pathol Pharmacol, 43:519-522
\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Frackiewicz, E. J. et al. (2002), "Brasofensine treatment for parkinson's disease
	in combination with levodopa/carbidopa," Ann Pharmacother, 36(2):225-230
1/1/1	Fuller R. W. and Hemrick, S. K. (1985), "Effects of amfonelic acid α-methyltyrosine, Ro4-1284 and haloperidol pretreatment on the depletion of
	striatal dopamine by 1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine in mice," Res
	Comm Chem Ophthalmol Pharmacol, 48(1):17-25
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ATTY DOCKET NO. 47-00B	SERIAL NO. 10/616/692	FILING DATE July 9, 2003
APPLICANT J. Nelson	<del></del>	GROUP 1614

_	
	Furukawa, N. et al. (2001), "Endogenously released dopa is causal factor for
	glutamate release and resultant delayed neuronal bell death by transient
	ischemia in rat striata," J Neurochem, 76(3):815-824
	Geula, C. et al. (1994), "Cholinesterase activity in the plaques tangles and
	angiopathy of Alzheimer's disease does not emanate from amyloid," Brain Res,
[ PY ]	644(2):327-630
1	Glazer, W. M. et al. (1993), "Predicting the long-term risk of tardive dyskinesia in
	out-patients maintained on neuroleptic medications," J Clin Psych, 54(4):133-139
	Goodman, R. and Snyder, H. (1982), "K-opiate receptors localized by autography
) <b>)</b>	to deep layers of cerebral cortex: relation to sedative effects," Proc Natl Acad Sci
	USA, 79:5703-5707
	Goshima, Y. et al. (1993), "L-dopa induces Ca(2+)-dependent and tetrodotxin-
	sensitive release of endogenous glutamate from rat striatal slices," Brain Res,
	617(1):167-170
111	Herrero, M. T. et al. (1996), "Consequence of nigrostriatal denervation and I-dopa
	therapy on the expression of glutamic acid decarboxylase messenger RNA in the
1 1/3	pallidum," Am Acad Neurol, 47(1):219-224
	Hillier, C. E. et al. (Feb. 1999), "Thalamotomy for severe antipsychotic induced
	tardive dyskinesia and dystonia," J. Neurol. Neurosurg. Psychiatry 66:250-251
	Hirsch, E. (2000), "Nigrostriatal system plasticity in parkinson's disease: effect of
1 1/7/2/ 1	dopaminergic denervation and treatment," <i>Ann Neurol</i> , 47(suppl 1):S155
	Hughes, N. et al. (1998), "Kappa-opioid receptor agonists increase locomotor
1111	activity in the monoamine depleted rat model of parkinsonism," Mov Disord,
	13(2):228
	Iravani, M. M. et al. (2001), "GDNF reverses priming for dyskinesia in MPTP-
	treated, I-dopa primed common marmosets," Euro J Neurosci, 13(3):597-608
	Iverson, L.L. and Kelly, J.S. (1975), "Uptake and metabolism of γ-aminobutyric
	acid by neurons and glial cells, " Biochem Pharmaco, 24:993-998
	Jarosinski, K. W. et al. (2001), "Specific deficiency in nuclear factor κΒ activation
	in neurons of the central nervous system," Lab Invest, 81(9):1275-1288
	Jenner, P. (2000), "Factors influencing the onset and persistence of dyskinesia in
XX .	MPTP treated primates," Ann Neurol, 47(suppl 1):S90-S104
	Jenner, P. (2002), "Pharmacology of dopamine agonists in the treatment of
XW	Parkinson's disease," Am Acad Neurol, 58(4):suppl 1 S1-S8
	Jindal, M. N. et al. (1960), "Local anesthetic action of antimalarials (chloroquine
	and amodiaquine)" Arch Int Pharmacodyn 127:132-140
	Jindal, M. N. (1970), "Adrenergic neurone blockade with chloroquine and
	amodiaquine," Br J Med, 58(8):1050-1056
	Johansson, P. E. et al. (1990), "Neuropeptide changes in a primate model (cebus
	apella) for tardive dyskinesia," Neurosci, 37(2):563-567
	Kane, J.M., "Tardive dyskinesia: epidemiological and clinical presentation,"
	(1995) Psychopharmacology: The Fourth Generation of Progress, 1485-1495
	Kingsbury, A. E. et al. (1998), "DNA fragmentation in human substantia nigra:
XM	apoptosis or perimortem effect?" Mov Disord, 13(6):877-884
17 X / -	Klawans, H. and Shenker, D. (1970), "Theoretical implications of the use of I-
<b>  Y</b>	dopa in parkinsonism," Acta Neurol Scand, 46:409-441
711	Klawans, H. L. (1973), "The pharmacology of tardive dyskinesias" Am J Psych,
	130(1):82-86.
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ATTY DOCKET NO. 47-00B	SERIAL NO. 10/616/692	FILING DATE July 9, 2003
APPLICANT J. Nelson		GROUP 1614

1	
	Kure, S. et al. (1991), "Glutamate triggers internucleosomal DNA cleavage in neural cells," Biochem & Biophysical Res Comm, 179(1):39-45
	Kurnick, N. B. and Radcliffe, I. E. (1962), "Reaction between DNA and quinacrine
	and other antimalarials," J Lab & Clin Med, 60(4):669-688
	Ladipo, G. O. et al. (1983), "Complete heart block in chronic chloroquine peisoning," Int J Cardiol, 4:198-200
À	Lang, A. E. (2000), "Surgery for levodopa induced dyskinesias," Ann Neurol, 47(suppl 1): S193-S202
	Langston, J.W., (1986) "MPTP-induced Parkinsonism: how good a model is it?" Recent Dev. In Parkinson's Disease, 119-126
X	Law, P. Y. et al. (1984), "Down-regulation of opiate receptor in neuroblastoma x glioma NG 108-15 hybrid cells," <i>J Biol Chem</i> , 259(14):4096-4104
	Lee, H. J. et al. (2001), "Anti-apoptotic role of NF-kappaB in auto-oxidized dopamine induced apoptosis of PC12 cells," <i>Journal of Neurochemistry</i> , 76(2):602-609
	Lieberman, J. A. et al. (1997), "Neurochemical sensitization in the pathophysiology of schizophrenia deficits and dysfunction in neuronal regulation and plasticity," <i>Neuropsychopharmacology</i> , 17:205-229
	Lim, L. Y. and Go, M. L. (1986), "The anticholinesterase activity of mefloquine," Clin Exp Pharmacol Physiol, 13(6):527-531
	Lindefors, N. (1993), "Dopaminergic regulation of glutamic acid decarboxylase mRNA expression and GABA release in the striatum," <i>Prog Neurol Psychopharmacol &amp; Biol Psych</i> , 17(6):887-903
(i)	Lipsky, R. H. et al. (2001), "Nuclear factor kappaB is a critical determinant in N-methyl-d-aspartate receptor mediated neuroprotection," <i>J Neurochem</i> , 78(2):254-264
	Liu, L. et al.1990), "Interactions of chloroquine with benzodiazepine, gamma-aminobutyric acid and opiate receptors," <i>Biochem Pharma</i> , 41(10):1534-1536
(N)	Lozano, A. M. et al. (2000), "Neuronal recording in parkinson's disease patients with dyskinesias induced by apomorphine," <i>Ann Neurol</i> , 47(suppl 1):S142-S146
	Luo, J. et al. (2002), "Subthalamic GAD gene therapy in a parkinson's disease rat model," Science, 298(5592):425-429
M	Maeda, T. et al. (1997). "L-DOPA neurotoxicity is mediated by glutamate release in cultured rat striatal neurons," <i>Brain Res</i> , 771(1):159-162
A	Maneuf, Y.P. et al., (1995) "Functional implications of kappa opioid receptor- mediated modulation of glutamate transmission in the output regions of the basal ganglia in rodent and primate models of Parkinson's disease," <i>Brain Research</i> 683:102-108
A	Mangelus, M. et al. (2001), "Involvement of nuclear factor kappa B in endothelin a receptor induced proliferation and inhibition of apoptosis," <i>Cell Mol Neurobiol</i> , (6):657-674
	Manson, A.J. et al., "High dose naltrexone for dyskinesias induced by levodopa," (2001) J. Neurol. Neurosurg. Psychiatry 70:554-556
	Martin, B. C. et al. (2001), "Antipsychotic prescription use and costs for persons with schizophrenia in the 1990s: current trends and five year time series forecasts," <i>Schizo Res</i> , 47(2-3):281-292

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Form PTO 1449		
ATTY DOCKET NO. 47-00B	SERIAL NO. 10/616/692	FILING DATE July 9, 2003
APPLICANT J. Nelson	<u></u>	GROUP 1614

<del></del>	
	Mavridis, M. and Besson, M. J. (1999), "Dopamine-opiate interaction in the
	regulation of neostriatal and pallidal neuronal activity as assessed by opioid
	precursor peptides and glutamate decarboxylase messenger RNA expression,"
	Neurosci, 92(3):945-966
$\mathbb{N}^{1}$	Mitchell, I. J. et al. (1985), "Sites of the neurotoxic action of 1-methyl-4-phenyl-
	1,2,3,6-tetrahydropyridine in the macaque monkey include the ventral tegmental
	area and the locus ceruleus," Neurosci Lett, 61:195-200
	Mitchell, I.J. and Carroll, C.B. (1997), "Reversal of Parkinson's disease symptoms
	in primates by antagonism of excitatory amino acid transmission, potential
77,	mechanisms of action," Neurosci & Behav Res, 21(4):469-475
	Mitchell, I. J. et al. (1994), "Glutamate-induced apoptosis results in a loss of
	striatal neurons in the parkinsonian rat," Neurosci, 63(1):1-5
1/11	Mitchell, I. J. et al. (1985), "Subcortical changes in the regional uptake of [3H]-2-
	deoxyglucose in the brain of the monkey during experimental choreiform
	dyskinesia elicited by injection of a gamma aminobutyric acid antagonist into the
	subthalamic nucleus," Brain, 108(Pt.2):405-422
	Mitchell, I. J. et al. (1992), "A 2-deoxyglucose study of the effects of dopamine
	agonists on the parkinsonian primate brain implications for the neural
	mechanisms that mediate dopamine agonist induced dyskinesia," <i>Brain</i> , (Pt
	3):809-824
	Mitchell, I. J. et al.(1992), "Regional changes in 2-deoxyglucose uptake
	associated with neuroleptic induced tardive dyskinesia in the cebus monkey,"
VV	Mov Disord, 7(1):32-37
	Mitchell, I. J. et al. (1986), "Neural mechanisms mediating 1-methyl-4-phenyl-
NA - I	1,2,3,5-tetrahydropyridine-induced parkinsonism in the monkey relative
	contributions of the striatopallidal and striatonigral pathways as suggested by 2-
	deoxyglucose uptake," <i>Neurosci Lett</i> , 63:61-65
<del>                                     </del>	
1111	Mitchell, I. J. et al. (1989), "Neural mechanisms underlying parkinsonian
	symptoms based upon regional uptake of 2-deoxyglucose in monkeys exposed to
	1-methyl-4-phenyl-1,2,6-tetrahydropridine," Neurosci, 32(1):213-226
	Miyachi, Y. et al. (1986), "Antioxidant action of antimalarials," Ann Rheum
<del>- 24</del>	Disease, 45:244-248
1 ()++- 1	Morgenstern, H. and Glazer, W. M. (1993), "Identifying risk-factors for tardive
	dyskinesia among long-term outpatients maintained with neuroleptic
<del>  \                                   </del>	medications," Arch Gen Psych, 50:723-733
	Nandi, D. et al. (2002), "Reversal of akinesia in experimental parkinsonism by
1 M	GABA antagonist microinjections in the pedunculopontine nucleus," Brain,
	125(11):2418
11/1	Napier, T. C. and Mitrovic, I. (1999), "Opioid modulation of ventral pallidal inputs,"
NY .	NY Acad Sci, 877:176-201
\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Nutt, J. G. (2000), "Clinical pharmacology of levodopa-induced dyskinesia," Ann
WY	Neurol, 47(suppl 1):S160-S166
1 W	Obeso, J. et al. (2000), "Pathophysiology of levodopa-induced dyskinesias in
	parkinson's disease: problems with the current model," Ann Neurol, 47(suppl
M	1):S22-S34
	Ogura, M. and Kita, H. (2000), "Dynorphin exerts both postsynaptic and
T%(( )	presynaptic effects in the globus pallidus of the rat," J Neurophysiol, 83(6):3366-
	3376
7	1

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Form PTO 1449		
ATTY DOCKET NO. 47-00B	SERIAL NO. 10/616/692	FILING DATE July 9, 2003
APPLICANT J. Nelson		GROUP 1614

M	Olanow, C.W. and Obeso, J. A. (2000), "Preventing levodopa induced dyskinesias," <i>Ann Neurol</i> , 47(suppl 1):S167-S178
W	O'Shaughnessy, T.J. et al. (2003, "Acute neuropharmacologic action of chloroquine on cortical neurons in vitro," <i>Brain Res</i> , <b>959</b> :280-286
W	Osifo, N. (1979), "Drug-related transient dyskinesias," Clin Pharma & Therap, 25(6):767-771
	Ostermeier, A. et al. (2000), "Activation of mu- and delta-opioid receptors causes presynaptic inhibition of glutamatergic excitation in neocortical neurons," Anesthesiol, 93(4):1053-1063
AT	Pahl, J. L. et al. (1995), "Positron-emission tomography in tardive dyskinesia," J Neuropsych, 7:457-465
	Pandya, K. H. et al. (1968), "Mechanism of supersensitivity to catecholamines following chloroquine," <i>Arzneimittelforschung</i> , 18(7):786-790
X	Perlmutter, J. S. et al. (1997), "MPTP induces dystonia and parkinsonism: clues to the pathophysiology of dystonia," <i>Am Acad Neurol</i> , 49(5):1432-1438
	Piccini, P. et al. (1997), "Alterations in opioid receptor binding in parkinson's disease patients with levodopa induced dyskinesias," <i>Ann Neurol</i> , 42(5):720-726
pt	Rascol, O. (2000), "Medical treatment of I-dopa induced dyskinesias," <i>Ann Neurol</i> , 47(suppl 1):S179-S188
	Rascol, O. et al. (1994), "Nattrexone, an opiate antagonist, fails to modify motor symptoms in patients with Parkinson's disease," Movement Disorders, 9:437-440
A	Reddy, R. D. and Yao, J. K. (1996), "Free Radical pathology in schizophrenia: a review," Free Rad Pathol, 33-43
XT	Richardson, P. J. (2001), "The adenosine A <sub>2A</sub> receptor of the basal ganglia," <i>J Physiol</i> , 532(2):284-288
	Rinne, U. K. et al. (1990), "Positron emission tomography demonstrates dopamine D <sub>2</sub> receptor supersensitivity in the striatum of patients with early parkinson's disease" <i>Mov Disord</i> , 5(1):55-59
(KK)	Rinne, U. K. et al. (1983), "Brain enkephalin receptors in parkinson's disease," <i>J Neural Transmiss</i> , Supp. 19:163-171
	Rodnitzky, R. L. (2002), "Drug-induced movement disorders," Clin Neuropharmacol, 25(3):142-152
	Ross, S. B. (1995), "Comparison of high-affinity binding of <sup>3</sup> H proadifen and <sup>3</sup> H (-)-cocaine to rat live membranes," <i>Pharmacol &amp; Toxicol</i> , 76(2):141-145
RAF	Rupp, A. and Keith, S. J. (1993), "The costs of schizophrenia: assessing the burden," <i>Psych Clin N Am</i> , 16:413-423
	Sarre, S. et al. (1997), "Biotransformation of locally applied precursors of dopamine, serotonin and noradrenaline in striatum and hippocampus: a microdialysis study," <i>J Neural Transm</i> , 104:1215-1228
Att	Schwartz, J. C. et al. (1993), "Dopamine D <sub>3</sub> receptor: basic and clinical aspects," Clin. Neuropharmacol. 16(4):295-314
W	Schwartz, J. C. et al.(1998), "Functional implications of multiple dopamine receptor subtypes: the D <sub>1</sub> /D <sub>3</sub> receptor coexistence," <i>Brain Research</i> , 26(2-3):236-242
X	Seeman, P. and Kapur, S. (1997), "Clozapine occupies high levels of dopamine d2 receptors," <i>Life Sci</i> , 60(12):207-216
	Sheridan, R. et al. (1997), "Structural features of aminoquinolines necessary for antagonist activity against botulinum neurotoxin," <i>Toxicon</i> , 34(9):1439-1451

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Form PTO 1449		
ATTY DOCKET NO. 47-00B	SERIAL NO. 10/616/692	FILING DATE July 9, 2003
APPLICANT J. Nelson	<del></del>	GROUP 1614
<b></b>		

M		Shindou, T. et al. (2000), "Adenosine A <sub>2A</sub> receptor enhances GABA <sub>A</sub> -mediated IPSCs in the rat globus pallidus," 532(2):432-434
X		Sodeyama, N. et al. (1999), "Association between butyrylcholin-esterase K variant and the Alzheimer neuropathological changes in apolipoprotein E (E4) carriers older than 75," J Neurol Neurosurg Psych, 67(5):693-694
		Sokoloff, P. et al. (1990), "Molecular cloning and characterization of a novel dopamine receptor (D <sub>3</sub> ) as a target for neuroleptics," <i>Nature</i> , 347:146-151
A		Stanford, I. M. and Cooper, A. J. (1999), "Presynaptic mu and delta opioid receptor modulation of GABAa IPSCs in the rat globus pallidus in vitro," <i>J Neurosci</i> , 19(12):4796-4803
R	-	Stern, Y. and Langston, J. W. (1985), "Intellectual changes in patients with MPTP-induced parkinsonism," <i>Neurol</i> , 35:1506-1509
X		Sugaya, Y. et al. (2001), "Autoradiographic studies using <sub>L</sub> -[¹⁴C]DOPA and – [³H]DOPA reveal regional Na⁺-dependent uptake of the neurotransmitter candidate <sub>L</sub> -DOPA in the CNS," <i>Neurosci</i> , 104(1):1-14
K		Szymanski, S. D. et al. (1996), "Vulnerability to tardive dyskinesia development in schizophrenia and <sup>F</sup> DG-PET study of cerebral metabolism,"  Neuropsychopharmacol, 15(6):567-575
K		Tanaka, M. et al. (2000), "Novel alternative promoters of mouse glial cell line- derived neurotrophic factor gene," <i>Biochimica et Biophysica Acta</i> , 1494(1-2):63-74
M		Tjalve, H. et al. (1981), "Studies on the binding of chlorpromazine and chloroquine to melanin in vivo," <i>Biochem Pharmacol</i> , 30(13):1845-1847
H		Tseng, L. and Collins, K. (1991), "Involvement of epsilon and kappa opioid receptors in the inhibition of the tail flick response induced by phenazocine in the mouse," <i>J Exp Ther</i> , 259:330-336
M		Wainer, I. W. et al. (1994), "Distribution of the enantiomers of hydroxychloroquine and its metabolites in ocular tissues of the rabbit after oral administration of racemic-hydroxychloroquine," <i>Chirality</i> 6:347-354
W		Waldmeier, P. C. (2003), "Prospects for anti-apoptotic drug therapy of neurodegenerative diseases," Nerv Sys Res, 27(2):303-321
W		Weber, S. M. et al. (2002), "Inhibition of mitogen activated protein kinase signaling by chloroquine," <i>J Immunol</i> , 168:5303-5309
M		Weber, S. and Levitz, S. M. (2000), "Chloroquine interferes with lipopolysaccharide-induced TNF-α gene expression by nonlysosomotropic mechanisms," <i>J Immunol</i> , 163(3):1534-1540
		Weetman, J. and Anderson, I. M. (1997), "Bilateral posteroventral pallidotomy for severe antipsychotic induced tardive dyskinesia and dystonia," <i>J Neurol Neurosurg &amp; Psych</i> , 63:417-418
and the		Weglicki, W. B. et al. (1993), "Modulation of cytokines and myocardial lesions by vitamin e and chloroquine in a Mg-deficient rat model," <i>Am. J. Cell Physiol</i> , 264(3):169-172
A		Witiak, D., Grattan, D., Heaslpi, R. and Rahwan, R. (1981), "Synthesis and preliminary pharmacological evaluation of asymmetric chloroquine analogues," <i>J Med Chem</i> , 24(6):712-717
W	+	Wolters, E. (1999), "Dopaminomimic psychosis in parkinson's disease patients: diagnosis and treatment," <i>Neurol</i> , 52(7):S10-S13;

Prophe C. Jones

2/2/06

Form PTO 1449		
ATTY DOCKET NO. 47-00B	SERIAL NO. 10/616/692	FILING DATE July 9, 2003
APPLICANT J. Nelson		GROUP 1614

	Yabe, T. et al.(2001), "NF kappa B activation is required for the neuroprotective effects of pigment epithelium derived factor (PEDF) on cerebellar granule neurons," J Bio Chem, 276(46):43313-43319					
JAN 1	Yao, J. K. et al. (2001), "Oxidative damage and schizophrenia: An overview of the evidence and its therapeutic implications," CNS Drugs, 15(4):287-310					
M	You, Z. B. et al. (1999), "Modulation of neurotransmitter release in the basal ganglia of the rat brain by dynorphin peptides," <i>J Pharmacol &amp; Exp Therap</i> 290(3):1307-1315					
0.1	Youdim, M. B. et al. (1994), "The enigma of neuromelanin in parkinson's disease substantia nigra," <i>J Neural Transm</i> , 43(suppl):113-122					
7	Yu, P. (2002), "Brasofensine neuro search," Cur Opin Invest Drugs, 1(4):504-508					
Left	Yu, S. P. et al.(1999), "NMDA receptor mediated K+ efflux and neuronal apoptosis," Science, 284(5412):336-339					
1/4/	Zaheer, A. et al. (2001), "Effects of glia maturation factor over expression in					
	primary astrocytes on MAP kinase activation, transcription factor activation and neurotrophin secretion," Neurochem Res, 26(12):1293-1299					
<b>*</b>	Zamir, N. et al. (1984), "Primate model of parkinson's disease: alterations in multiple opioid systems in the basal ganglia," <i>Brain Res</i> , 322(2):356-360					
	Books					
	Merritt's Textbook of Neurology, (1995), 9 <sup>th</sup> Ed, Williams & Wilkins, Baltimore, MD, "Movement disorders" pp. 713-730					
W	Sigma-Aldrich (2002), "Pain and Mechanisms of Analgesia," Catalog # FIO 356-500947 0112					
V	Electronic Resources					
j	"Chloroquine", "Sinemet" & "Levodopa" MicroMedex Healthcare Series, http://phantom.uchsc.edu/mdxcgi/diSYS&SET=485440&SYS=1&T=358&D=16 92					
N. C.	"National Institute of Neurological Disorders and Stroke" Parkinson's disease: A research planning workshop, <a href="http://www.ninds.hih.govhealinfo/diorder/parkinso/pdreport/pftherapy.ntm">http://www.ninds.hih.govhealinfo/diorder/parkinso/pdreport/pftherapy.ntm</a>					
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#### **U.S. PATENT DOCUMENTS**

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#### **FOREIGN PATENT DOCUMENTS**

	Document Number	Date	Country	Class	Subclas s	Translation Yes/No
						į

CHASE, T. M. et al., "Striatal mechanisms and papthogenesis of Parkinsonian signs and motor complications," (April 2000) Annals of Neuroloogy 46(1):S122-S130

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609, Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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ATTY DOCKET NO. 47-00B	SERIAL NO. 10/616,692	FILING DATE July 9, 2003			
APPLICANT Nelson		GROUP 1614			

## **U.S. PATENT DOCUMENTS**

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# FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation Yes/No

OTHER PRIOR ART (including Author, Title, Date, Pertinent Pages, etc.)

	 <del>, , , , ,</del>	IDA I AION ANT (including Author, Time, Dute, Tertinent Fuges, etc.)
1	1	Abiose, A.K. et al., "Chloroquine-induced venodilation in human hand veins," (1997) Clin. Pharm. & Therapeutics 61(6):677-683
9	2	Antonini, A. et al., "Differential diagnosis of Parkinsonism with [18F]Fluorodeoxyglucose and PET," (1998) Movement Disorders 13(2):268-274
	2A	Ardueser, G.A. and Heim, H.C., "Some effects of chloroquine on oxidative processes in rat heart," (1967) J. Pharmaceutical Sciences 56(2):254-258
	3	Baltzan, M. et al., "Randomized trial of prolonged chloroquine therapy in advanced pulmonary sarcoidosis," (1999) Am. J. Respir. Crit. Care Med. 160:192-197
	4	Behl, C. et al., "Hydrogen peroxide mediates amyloid β protein toxicity," (1994) Cell 77:817-827
	5	Ben-Shachar, D. and Youdim, M.B.H., "Selectivity of melaninized nigra-striatal dopamine neurons to degeneration in Parkinson's disease may depend on iron-melanin interaction," (1990) J. Neural Transm. 29:251-258
	6	Ben-Shachar, D. et al., "The iron chelator desferrioxamine (Desferal) retards 6-hydroxydopamine-induced degeneration of nigrostriatal dopamine neurons," (1991) J. Neurochemistry 56(4):1441-1444
	7	Bergendi, L'. et al., "Chemistry, physiology and pathology of free radicals," (1999) Life Sciences 64(18-19):1865-1874
V	8	Bitonti, A.J. et al., "Reversal of chloroquine resistance in malaria parasite plasmodium falciparum by desipramine," (1988) Science 241:1301-1303

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Page 1 of 9

Form PTO 1449		
ATTY DOCKET NO. 47-00B	SERIAL NO. 10/616,692	FILING DATE July 9, 2003
APPLICANT Nelson		GROUP 1614

(C	1		T
		8A	Booij, J. et al., "[1231]FP-CIT SPECT shows a pronounced decline of striatal dopamine transporter labelling in early and advanced Parkinson's disease," (1997) J. Neurol. Neurosurg. Psychiatry 62:133-140
Υ_		9	Bowen, B.C. et al., "Proton MR spectroscopy of the brain in 14 patients with Parkinson's disease," (1995) Am. J. Neuroradiology 161(1):61-68
		10	Burke, R.E., "Programmed cell death and Parkinson's disease," (1998) Movement Disorders 13(S1):17-23
		11	Byrd, T.F. and Horowitz, M.A., "Chloroquine inhibits the intracellular multiplication of Legionella pneumophila by limiting the availability of iron. A potential new mechanism for the therapeutic effect of chloroquine against intracellular pathogens," (1991) J. Clin. Investigation 88(1);351-357
		12	Carlsson, Arvid, "Development of new pharmacological approaches in Parkinson's disease," (1986) Advances in Neurology 45:513-518
		13	Chan, P.C. and Bielski, B.H., "Enzyme-catalyzed free radical reactions with nicotinamide adenine nucleotides. II. Lactate dehydrogenase-catalyzed oxidation of reduced nicotinamide adenine dinucleotide by superoxide radicals generated by xanthine oxidase," (1974) J. Biol. Chem. 249(4):1317-1319
		14	Cho, Y.W. and Aviado, D.M., "Pathologic physiology and chemotherapy of plasmodium berghei. IV. Influence of chloroquine on oxygen uptake of red blood cells infected with sensitive or resistant strains," (1968) Exp. Parasitology 23(2):143-150
-		15	Chrichton, R.R. and Ward, R.J., "Iron metabolism - new perspectives in view," (1992) Biochemistry 31(46):11255-11264
		16	Chrischilles, E.A. et al., "The health burdens of Parkinson's disease," (1998) Movement Disorders 13(3):406-413
		17	Cotzias, G.C. et al., "Melanogenesis and extrapyramidal diseases," (1964) Chemistry in Medicine 23:713-718
		18	Culvenor, J.G. et al., "Non-Aβ component of Alzheimer's disease amyloid (NAC) revisited," (1999) Am. J. Pathology 155:1173-1181
	,	19	Cummings, J.L., "Depression and Parkinson's Disease: A Review," (1992) Am. J. Psychiatry 149(4):443-454
$\bigvee$		20	Dailly, E. et al., "Chain-breaking antioxidants and ferriheme-bound drugs are synergistic inhibitors of erythrocyte membrane peroxidation," (1998) Free Radical. Res. 28(2):205-214

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2/21/06

Page 2 of 9

Form PTO 1449			
ATTY DOCKET NO. 47-00B SERIAL NO. 10/616,692 FILING DATE July 9, 2003			
APPLICANT Nelson		GROUP 1614	

	21	D'Amato, R.J. et al., "Selectivity of the Parkinsonian neurotoxin MPTP: toxic metabolite MPP* binds to neuromelanin," (1986) Science 231:987-989
	22	D'Amato, R.J. et al., "Evidence for neuromelanin involvement in MPTP-induced neurotoxicity," (1987) Nature 327:324-326
9	23	Davison, A.J. and Gee, P., "Redox state of cytochrome C in the presence of the 6-hydroxydopamine/oxygen couple: oscillations dependent on the presence of hydrogen peroxide or superoxide," (1984) Arch. Biochem. and Biophysics 233(2):761-771
	24	Debing, I. et al., "Melanosome binding and oxidation-reduction properties of synthetic L-dopa-melanin as in vitro tests for drug toxicity," (1988) Mol. Pharmacology 33(4):470-476
	25	De Duve, C. et al., "Lysosomotropic agents," (1974) Biochem. Pharm. 23:2495-2531
	26	Deepalakshmi, P.D. et al., "Effect of chloroquine on rat liver mitochondria," (1994) Indian J. Exp. Biology 32(11):797-799
	27	De Feo, P. et al., "Chloroquine reduces whole body proteolysis in humans," (1994) Am. J. Physiology 267:E183-E186
	28	Dethy, S. et al., "Asymmetry of basal ganglia glucose metabolism and dopa responsiveness in Parkinsonism," (1998) Movement Disorders 13(2):275-280
	29	Dexter, D.T. et al., "Basal lipid peroxidation in substantia nigra is increased in Parkinson's disease," (1989) J. Neurochem. 42(2):381-389
	30	Di Monte, D.A. et al., "Astrocytes as the site for bioactivation of neurotoxins," (1996) NeuroToxicology 17(3-4):697-704
	31	Farid, M.A., "The malaria campaign - why not eradication?" (1998) World Health Forum 19:417-427
	32	Fridovich, I., "Superoxide dismutases," (1975) 147-159
	33	Fukushima, T. et al., "Radical formation site of cerebral complex I and Parkinson's disease," (1995) J. Neuroscience Res. 42:385-390
-	34	German, D.C. et al., "1-methyl-4-phenyl-1,2,3,6-tetra-hydropyridine-induced Parkinsonian syndrome in macaca faxcicularis: which midbrain dopaminergic neurons are lost?" (1988) Neuroscience 24(1):161-174
$\bigvee$	35	Ghigo, D. et al., "Chloroquine stimulates nitric oxide synthesis in murine, porcine, and human endothelial cells," (1998) J. Clin. Invest. 102(3):595-605

hoghe C. Jones

2/21/06

Page 3 of 9

Form PTO 1449					
ATTY DOCKET NO. 47-00B	SERIAL NO. 10/616,692	FILING DATE July 9, 2003			
APPLICANT Nelson		GROUP 1614			

W	36	Gibb, W.R.G. and Lees, A.J., "Anatomy, pigmentation, ventral and dorsal subpopulations of the substantia nigra, and differential cell death in Parkinson's disease," (1991) J. Neurology, Neurosurgery, and Psychiatry 54:388-396
	37	Glinka, Y.Y. and Youdim, M.B.H., "Inhibition of mitochondrial complexes I and IV 6-hydroxydopamine," (1995) Eur. J. Pharmacology Environ. Toxicol. Pharmacol. Section 292, 329-332
	38	Glinka, Y. et al., "Nature of inhibition of mitochondrial respiratory complex I by 6-hydroxydopamine," (1996) J. Neurochemistry 66(5):2004-2010
	39	Golbe, L.I., "Alpha-synuclein and Parkinson's disease," (1999) Movement Disorders 14(1):6-9
	40	Goldstein, M. and Lieberman, A., "The role of the regulatory enzymes of catecholamine synthesis in Parkinson's disease," (1992) Neurology 42(S4):8-12
	41	Gotham, A.M. et al., "Levodopa treatment may benefit or impair 'frontal' function in Parkinson's disease," (1986) <i>Lancet</i> 25;2(8513):970-971
	42	Graham, D., "Catecholamine toxicity: A proposal for the molecular pathogenesis of manganese neurotoxicity and Parkinson's disease," (1984) <i>Toxicology</i> 5(1):83-96
	43	Graham, D.G., "Oxidative pathways for catecholamines in the genesis of neuromelan and cytotoxic quinones," (1978) Molecular Pharmacology 14:633-643
	44	Graham, D.G., "Autoxidation versus covalent binding of quinones as the mechanism toxicity of dopamine, 6-hydroxydopamine, and related compounds toward C1300 neuroblastoma cells in vitro" (1978) Molecular Pharmacology 14:644-653
	45	Hall, S. et al., "MRI, brain iron and experimental Parkinson's disease," (1992) J. Neurological Sci. 198-208
	46	Hirsch, E. et al., "Melanized dopaminergic neurons are differentially susceptible to degeneration in Parkinson's disease," (1988) <i>Nature</i> 334:345-348
	47	Hirsch, E.C. and Faucheux, B.A., "Iron metabolism and Parkinson's disease," (1998) Movement Disorders 13(S1):39-45
	48	Ivanina, T.A. et al., "A study of the mechanisms of chloroquine retinopathy," (1989) Ophthalmic Res. 21:216-220
	49	Ivanova, S. et al., "Cerebral ischemia enhances polyamine oxidation: identification of enzymatically formed 3-aminopropanal as an endogenous mediator of neuronal and glial cell death," (1998) J. Exp. Med. 188(2):327-340
	50	Jackson, M.J. et al., "Inhibition of lipid peroxidation in muscle homogenates by phospholipase A2 inhibitors," (1984) <i>Bioscience Reports</i> 4(7):581-587 (abstract only

Page 4 of 9

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Form PTO 1449					
ATTY DOCKET NO. 47-00B	SERIAL NO. 10/616,692	FILING DATE July 9, 2003			
APPLICANT Nelson		GROUP 1614			

		<b>T</b>
W.	51	Jenner, P., "Oxidative stress in Parkinson's disease and other neurodegenerative disorders," (1996) Pathologie Biologie 44(1):57-64
$V_1$	52	Jenner, P. et al., "Understanding cell death in Parkinson's disease," (1998) Annals of Neurology 44(1):S72-S84
	53	Karmazyn, M. et al., "The mechanism of coronary artery spasm: roles of oxygen, prostaglandins, sex hormones and smoking," (1979) Medical Hypothesis 5:447-452
	54	Kienzl, E. et al., "Iron as catalyst for oxidative stress in the pathogenesis of Parkinson's disease?" (1999) Life Sci 65(18-19):1973-1976
	55	Koller, W.C., "When does Parkinson's disease begin?", (1992) Neurology 42(S4):27-31
	56	Krogstad, D.J. and Schlesinger, P.H., "Acid-vesicle function, intracellular pathogens, and the action of chloroquine against plasmodium falciparum," (1987) N.E. J. Med. 317(9):543-549
	57	Langston, J.W. et al., "Pargyline prevents MPTP-induced Parkinsonism in primates," (1984) Science 225:1480-1482
	58	Langston, J.W., "MPTP neurotoxicity: an overview and characterization of phases of toxicity," (1985) Life Sciences 36:201-206
	59	Larsson, B. and Tjälve, H., "Studies on the mechanism of drug-binding to melanin," (1979) Chemical Pharmacology 28:1181-1187
	60	Leahy, F. et al., "Desquamative interstitial pneumonia responsive to chloroquine," (1985) Clinical Pediatrics 24(4):230-232
	61	Legssyer, R. et al., "Effect of chronic chloroquine administration on iron loading in the liver and reticuloendothelial system and on oxidative responses by the alveolar macrophages," (1999) Biochem. Pharmacology 57(8):907-911
	62	Lieberman et al., "Does selegiline provide a symptomatic or a neuroprotective effect?", (1992) Neurology 42(S4):41-48
	63	Lin, A.M-Y et al., "Striatal dopamine dynamics are altered following an intranigral infusion of iron in adult rats," (1998) Free Radical Biology & Medicine 24(6):988-993
	64	Linnik, M.D. et al., "Evidence supporting a role for programmed cell death in focal cerebral ischemia in rats," (1993) Stroke 24(12):2002-2009
	65	Loo, D.T. et al., "Apoptosis is induced by β-amyloid in cultured central nervous system neurons," (1993) <i>Proc. Natl. Acad. Sci. USA</i> 90:7951-7955
$\bigcup$	66	Lyden, A. et al., "Studies on the melanin affinity of haloperidol," (1982) Arch. Int. Pharmacodyn. Ther. 259(2):230-243

lwayne C. Jones.

2/2/06

Page 5 of 9

Form PTO 1449					
ATTY DOCKET NO. 47-00B	SERIAL NO. 10/616,692	FILING DATE July 9, 2003			
APPLICANT Nelson		GROUP 1614			

67	Magwere, T. et al., "Effects of chloroquine treatment on antioxidant enzymes in rat liver and kidney," (1997) Free Radical Biology & Medicine 22(1-2):321-327			
68	Makarenko, I.E. and Levitsky, E.P., "Resoquin in the clinic of internal illnesses, and the possible side effects of its use," (1950)			
69	Maret, G. et al., "The MPTP story: MAO activates tetrahydropyridine derivatives to toxins causing Parkinsonism," (1990) Drug Metabolism Reviews 22(4):291-332			
70	Martin, W.R.W. et al., "Increasing striatal iron content associated with normal aging," (1998) Movement Disorders 13(2):281-286			
71	Matsubara, K. et al., "Beta-carbolinium cations, endogenous MPP* analogs, in the lumbar cerebrospinal fluid of patients with Parkinson's," (1995) Neurology 45(12):2240-2245			
72	Meerson, F.Z. et al., "Prevention of stress disorders of myocardial contractile function using membrane protectors," (1983) Kardiologiia 23(7):86-90 (abstract and translation in English)			
72A	Mena, M.A., "Pharmacokinetics of L-DOPA in patients with Parkinson's Disease," (1986) Advances in Neurology 45:481-486			
73	Merad-Boudia, M. et al., "Mitochondrial impairment as an early event in the process of apoptosis induced by glutathione depletion in neuronal cells: relevance to Parkinson's disease," (1998) Biochem. Pharmacology 56:645-655			
74	Mielke, J.G. et al., "Chloroquine administration in mice increases beta-amyloid immunoreactivity and attenuates kainate-induced blood-brain barrier dysfunction," (1997) Neuroscience Lett. 227(3):169-172			
74A	Minotti, G. and Aust, S.D., "The requirement for iron (III) in the initiation of lipid peroxidation by iron (II) and hydrogen peroxide," (1987) J. Biological Chemistry 262(3):1-98-1104			
75	Mizuno, Y. et al., "Mitochondrial dysfunction in Parkinson's disease," (1998) Annals of Neurology 44(S1):S99-S109			
76	Monteiro, H.P. and Winterbourn, C.C., "6-hydroxydopamine releases iron from ferritin and promotes ferritin-dependent lipid peroxidation," (1989) <i>Biochem. Pharm.</i> 38(23):4177-4182			
77	Mytilineou, C. et al., "L-(—)-desmethylselegiline, a metabolite of selegiline [L-(—)-deprenyl], protects mesencephalic dopamine neurons from excitotoxicity in vitro," (1997) J. Neurochemistry 68(1):434-436			
78	Navas, P. et al., "Decrease of NADH in HeLa cells in the presence of transferrin or ferricyanide," (1986) Biochem. and Biophys. Res. Communications 135(1):110-115			

Page 6 of 9

hispie c. Jones

2/2/06

Form PTO 1449						
ATTY DOCKET NO. 47-00B SERIAL NO. 10/616,692 FILING DATE July 9, 2003						
APPLICANT Nelson GROUP 1614						

1	79	Nicklas, W.J. et al., "Inhibition of NADH-linked oxidation in brain mitochondria by 1-methyl-4-phenyl-pyridine, a metabolite of the neurotoxin, 1-methyl-4-phenyl-1,2,5,6-tetrahydropyridine," (1985) <i>Life Sciences</i> 36:2503-2508
V	80	Okamoto, M. et al., "Internucleosomal-DNA cleavage involved in ischemia-induced neuronal death," (1993) Biochem. and Biophys. Res. Communications 196(3):1356-1362
9	81	Octave, J-N et al., "Iron uptake and utilization by mammalian cells. I: Cellular uptake of transferrin and iron," (1983) TIBS 217-220
	82	Olanow, C.W. and Calne, D., "Does selegiline monotherapy in Parkinson's disease act by symptomatic or protective mechanisms?" (1992) Neurology 42(S4):13-26
	83	Ornstein, M.H. and Sperber, K., "The antiinflammatory and antiviral effects of hydroxychloroquine in two patients with acquired immunodeficiency syndrome and active inflammatory arthritis," (1996) Arthritis Rheum. 39(1):157-161
N	84	Poewe, W.H. and Wenning, G.K., "The natural history of Parkinson's disease," (1998)  Annals of Neurology 44(S1):S1-S9
	85	Pratt, W.B. and Fekety, R., "Chemotherapy of malaria," <u>The Antimicrobial Drugs</u> , (1986) Oxford University Press, New York, Chapter 14:355-384
	86	Remblier, C. et al., "Lactic acid-induced increase of extracellular dopamine measured by microdialysis in rat striatum: evidence for glutamatergic and oxidative mechanisms," (1999) Brain Research 837:22-28
	87	Riederer, P. et al., "Transition metals, ferritin, glutathione, and ascorbic acid in Parkinsonian brains," (1989) J. Neurochemistry 52(2):515-520
	88	Rollema, H. et al., "In vivo intracerebral microdialysis studies in rats of MPP* analogues and related charged species," (1990) J. Med. Chem. 33:221-2230
	89	Rollema, H. et al., "MPP*-like neurotoxicity of a pyridinium metabolite derived from haloperidol: In vivo microdialysis and in vitro mitochondrial studies," (1994) J. Pharm. and Exp. Therapeutics 268(1):380-387
	89A	Rollema, H. et al., "Comparison of the effects of intracerebrally administered MPP* (1-methyl-4-phenylpyridinium) in three species: microdialysis of dopamine and metabolites in mouse, rat and monkey striatum," (1989) Neuroscience Letters 106:275-281
	90	Roos, R.A. et al., "Response fluctuations in Parkinson's disease," (1990) Neurology 40(9):1344-1346
	91	Schapira, A.H., "Oxidative stress in Parkinson's disease," (1995) Neuropathol. Appl. Neurobiol. 21(1):3-9

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Form PTO 1449		
ATTY DOCKET NO. 47-00B	SERIAL NO. 10/616,692	FILING DATE July 9, 2003
APPLICANT Nelson		GROUP 1614

1		
r	92	Spencer, J.P.E. et al., "Superoxide-dependent depletion of reduced glutathione by L-DOPA and dopamine. Relevance to Parkinson's disease," (1995) NeuroReport 6:1480-1484
N. Control of the con	93	Sperber, K. et al., "Hydroxychloroquine treatment of patients with human immunodeficiency virus type 1," (1995) Clinical Therapeutics 17(4):622-636
	94	Springer, C. et al., "Chloroquine treatment in desquamative interstitial pneumonia," (1987) Archives of Disease in Childhood 62:76-77
	95	Stepien, K.B. and Wilczok, T., "Studies of the mechanism of chloroquine binding to synthetic DOPA-melanin," (1982) <i>Biochem. Pharmacol.</i> 1;31(21):3359-3365
	96	Stoof, J.C. et al., "Leads for the development of neuroprotective treatment in Parkinson's disease and imaging methods for estimating treatment efficacy," (1999) Eur. J. Pharmacol. 375(1-3):75-86
	97	Swaiman, K.F. and Machen, V.L., "Chloroquine reduces neuronal and glial iron uptake," (1986) J. Neurochemistry 46(2):652-654
	98	Tipton, K.F. and Singer, T.P., "Advances in our understanding of the mechanisms of the neurotoxicity of MPTP and related compounds," (1993) <i>J. Neurochem.</i> 61(4):1191-1206
	99	Tjalve, H. et al., "Studies on the binding of chlorpromazine and chloroquine to melanin in vivo," (1981) Biochem. Pharmacol. 30(13):1845-1847
	100	Toole-Simms, W. et al., "Transplasma membrane electron and proton transport is inhibited by chloroquine," (1990) Biochem. International 21(4):761-769
	101	Vainshtok, A.B., "Treatment of Parkinsonism with delagil," (1972) Klin. Med (Mosk) 50(9):51-56
	102	Yong, V.W. et al., "Depletion of glutathione in brainstem of mice caused by N-methyl-4-phenyl-1,2,3,6-tetrahydropyridine is prevented by antioxidant pretreatment," (1986) Neuroscience Letters 63:56-60
	103	Youdim, M.B.H. et al., "Is Parkinson's disease a progressive siderosis of substantia nigra resulting in iron and melanin induced neurodegeneration?", (1989) <i>Acta Neurol. Scand.</i> 126:47-54
	104	Biochemistry, (1975) Lubert Stryer, Stanford University, W.H. Freeman and Company, San Francisco, CA
	105	"Chloroquine", Micromedex Healthcare Series, http://phantom.uchsc.edu/mdxcgi/diSYS&SET=485440&SYS=1&T=358&D=1692

Page 8 of 9

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Form PTO 1449						
ATTY DOCKET NO. 47-00B	SERIAL NO. 10/616,692	FILING DATE July 9, 2003				
APPLICANT Nelson		GROUP 1614				

W		106	Clinical Toxicology of Commercial Products (1984) Gosselin, Smith, Hodge, 5th Ed., Williams & Wilkins, Baltimore/London, II-245
		107	<u>Diagnostic Clinical Neuropsychology</u> (1997) Bigler, E. and Clement, P., 3 <sup>rd</sup> Ed., University of Texas Press, Austin, TX
		108	Fundamentals of Anatomy & Physiology (1995) Martini, Frederic H., 3 <sup>rd</sup> Ed., Prentice Hall, Englewood Cliffs, NJ
		109	The Merck Index, (1996) 12th Ed., Susan Budavari, Ed., Merck Research Laboratories, Inc., Whitehouse Station, NJ, "Chloroquine - 7-chloro-4-(4-diethylamino-1 methylbutylamino)quinoline," p. 2220
		109 A	The Merck Index, (1960) 7th Ed., P.G. Stecher, Ed., Merck & Co., Inc. Rahway, NJ
		110	Organic Chemistry, (1996) McMurry, John, 4th Ed., Brooks/Cole Publishing, an International Thomson Publishing Co., Pacific Grove, CA
		111	Physicians' Desk Reference, (1996) 50th Ed., Medical Economics Company, Inc., Montvale, NJ
		112	Physicians' Desk Reference, (2000) 54th Ed., Medical Economics Company, Inc., Montvale, NJ
		113	"Practical chemotherapy of Malaria," (1990) World Health Org. Technical Report Series No. 805, p. 141
	1 1	113 A	Russian Drug Index, 2d Ed., S. Jablonski, US Dept. HEW, Public Health Service Publication No. 814 (Revised 1967)
		114	Textbook of Medical Physiology (1996) Guyton, A.C. and Hall, J.E., 9th Ed., W.B. Saunders Company, Philadelphia, PA

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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ATTY DOCKET NO. 47-00B	SERIAL NO. 10/616,692	FILING DATE July 9, 2003
APPLICANT Nelson		GROUP 1614

## **U.S. PATENT DOCUMENTS**

Exmr. Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	6,015,555	01/18/00	Friden (abstract only)	424	133.1	
15	5,948,791	09/07/99	Hofheinz et al.	514	313	
W	5,834,505	11/10/98	Peters	514	454	
W	5,736,556	04/07/98	Moldt et al.	514	304	
	5,639,737	06/17/97	Rubin	514	53	
	5,624,938	04/29/97	Pernis	514	313	
	5,596,002	01/21/97	Hofheinz et al.	514	313	
	5,430,039	07/04/95	Roberts-Lewis et al.	514	297	
	5,210, 076	05/11/93	Berliner et al.	514	21	
	4,421,920	12/20/83	Baudouin et al.	546	163	

## **FOREIGN PATENT DOCUMENTS**

	Document Number	Date	Country	Class	Subclass	Translation Yes/No

OTHER PRIOR ART (including Author Title Date Pertinent Pages etc.)

	Augustijns, P. et al., "Stereoselective de-ethylation of chloroquine in rat liver microsomes," (1999) Eur. J. Drug Metabolism & Pharmacokinetics 24(1):105-108 (abstract only)
()	Augustijns, P. and Verbeke, N., "Stereoselective pharmacokinetic properties of chloroquine and de-ethyl-chloroquine in humans," (1993) Clin. Pharmacokinetics 24(3):259-269 (abstract only)
	Begley, D.J., "The blood-brain barrier: principles for targeting peptides and drugs to the central nervous system," (1996) J. Pharm. Pharmacol. 48(2):136-146
	De Boer, A.G. and Breimer, D.D., "The blood-brain barrier: clinical implications for drug delivery to the brain," (1994) J. R. Coll. Physicians Lond. 28(6):50-506

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Form PTO 1449					
ATTY DOCKET NO. 47-00B	SERIAL NO. 10/616,692	FILING DATE July 9, 2003			
APPLICANT Nelson		GROUP 1614			

Donatelli, P. eta I., "Stereoselective inhibition by chloroquine of histamine N-methyltransferase in the human liver and brain," (1994) Eur. J. Clin. Pharmacol. 47(4):345-349 (abstract only)
Ducharme, J. et al., "Enantioselective disposition of hydroxychloroquine after a single oral dose of the racemate to healthy subjects," (1995) <i>Brit. J. Clin. Pharmacol.</i> 40(2):127-133 (abstract only)
Ducharme, J. and Farinotti, R., "Clinical pharmacokinetics and metabolism of chloroquine. Focus on recent advances," (1996) Clin. Pharmacokinet. 31(4):257-74 (abstract only)
Scaria, P.V. et al., "Differential binding of the enantiomers of chloroquine and quinacrine to polynucleotides: implications for steroselective metabolism," (1993) <i>Biopolymers</i> 33(6):887-95 (abstract only)
Tago, C.N. and Ofori-Adjei, D., "Effects of chloroquine and its enantiomers on the development of rat embryos in vitro," (1995) <i>Teratology</i> 52(3):137-142 (abstract only)
Yatin, S.M. et al., "Alzheimer's amyloid beta-peptide associated free radicals increase rat embryonic neuronal polyamine uptake and ornithine decarboxylase activity: protective effect of vitamin E," (1999) Neuroscience Letters 263(1):17-20 (abstract only)

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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#### **U.S. PATENT DOCUMENTS**

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## **FOREIGN PATENT DOCUMENTS**

	Document Number	Date	Country	Class	Subclass	Translation Yes/No

OTHER PRIOR ART (including Author, Title, Date, Pertinent Pages, etc.)

M	Ambrozi et al. (1976) "L-Dopa and (-)-deprenil in the treatment of Parkinson's disease: long-term study," Br. J. Pharmacol. 58(3):423-424. Database CA on STN. Chem. Abstr., Vol. 86 (Columbus OH USA), abstract No. 133721
Ŋ	Golbe et al. (1993) "Vitamin E and Parkinson's disease," Vitam. E Health Dis., Packer et al. Eds., Dekker, New York, NY, pp. 787-797, Database CA on STN. Chem. Abstr., Vol. 119 (Columbus, OH, USA) abstract No. 71356
<b>y</b>	Hemmer et al. (1967) "Cerebral activity of an herbal preparation (Tebonin) from Ginko biloba," Arzneim-Forsch, 17(4):491-493, Database CA on STN. Chem. Abstr., Vol. 67 (Columbus, OH, USA) abstract No. 52644

EXAMINER

DATE CONSIDERED 2

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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ATTY DOCKET NO. 47-00B	SERIAL NO. 10/616,692	FILING DATE July 9, 2003
APPLICANT J. Nelson		GROUP 1614

Cited by Examiner in 09/615,639

## **U.S. PATENT DOCUMENTS**

Exmr. Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate

## **FOREIGN PATENT DOCUMENTS**

	Document Number	Date	Country	Class	Subclass	Translation Yes/No
		. <u>.</u>				

OTHER PRIOR ART (including Author, Title, Date, Pertinent Pages, etc.)

4	Montrastruc JL, 1991. Therapie, 46(4):293-303. Recent advances in the clinical pharmacology of Parkinson's disease.
	Lowrey BS, 1997, Pigment Cell Res. vol. 10(5):251-256. Modeling drug-melanin interaction with theoretical linear solvation energy relationships.
	Paramar RC et al. 2000, J. Postgrad Med. 46(1):29-30. Chloroquine induced parkinsonism.
	Webster et al., Biochem. Pharmacol. 1991, Vol. 42, pages S225-7. Antimalarial activity of optical isomers of quinacrine dihydrochloride against chloroquine-sensitive and resistant plasmodium faciparum in vitro.
	Haberkorn A et al., Tropenmed. Parasitol. 1979, Vol. 30, pages 308-312. Antimalarial activity of the optical isomers of chloroquine diphosphate.

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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APPLICANT J. Nelson		GROUP 1614					

Originally filed in 09/615,639

## U.S. PATENT DOCUMENTS

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## **FOREIGN PATENT DOCUMENTS**

	Document Number	Date	Country	Class	Subclass	Translation Yes/No
				:		

OTHER PRIOR ART (including Author, Title, Date, Pertinent Pages, etc.)

N I	Aisen, Paul S. (1997) "Inflammation and Alzheimer's Disease: Mechanisms and Therapeutic Strategies," <i>Gerontology</i> 43:143-149
	Bhatia, M.S. (1991), "Chloroquine-induced psychiatric complications," <i>British Journal of Psychiatry</i> 159(Nov):735 (Abstract)
	Bhatia, M.S. et al. (1988), "Capgras syndrome in chloroquine induced psychosis," Indian Journal of Psychiatry 30(3):311-313 (Abstract)
	Cockroft, K M. et al. (1996) "Cerebroprotective effects of aminoquanidine in a rodent model of stroke," Stroke 27(8):1393-1398
	Conference Proceedings, Stroke Drug Development: Bridging the Gap From Animal Research to Human Trials, March 6-7, 1999, Orlando, FL, Proceedings Transcripts, Side 2, #10
	Donatelli, P. et al. (1994) "Stereoselective inhibition by chloroquine of histamine N-methyltransferase in the human liver and brain," Eur. J. Clin. Pharmacol. 47:345-349
	Feuerstein, G.Z. and Wang, X. (2000) "Animal models of stroke," <i>Molecular Medicine Today</i> 6:133-135
	Garg, P. et al. (1990) "Toxic psychosis due to chloroquine - not uncommon in children," Clinical Pediatrics 29(8):448-450
,	Golden, G.T. (1992) "Systemic chloroquine protects against striatal dopamine depleciton induced by unilateral intra-nigral MPP+ injection in rats," Soc. Neurosci., (Abstract); letter from Dr. G.M. Alexander in regard thereto.
$\forall$	Good, M.I. and Shader, R.I. (1997) "Behavioral toxicity and equivocal suicide associated with chloroquine and its derivatives," Am. J. Psychiatry 134(7):798-801

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Form PTO 1449		
ATTY DOCKET NO. 47-00B	SERIAL NO. 10/616,692	FILING DATE July 9, 2003
APPLICANT J. Nelson		GROUP 1614

80	Good, M.I. and Shader, R.I.(1982) "Lethality and behavioral side effects of chloroquine," J. Clin. Psychopharmacology 2:40-46
	Hagihara, N. et al. (2000) "Vascular protection by chloroquine during brain tumor therapy with Tf-CRM107," Cancer Res. 60:230-234
	Lovestone, S. (1991), "Chloroquine-induced mania," British Journal of Psychiatry 159(Jul):164-165 (Abstract)
	Lowrey, A.H. et al., (1997) "Modeling Drug-melanin Interaction with Theoretical Linear Solvation Energy Relationships," <i>Pigment Cell Res.</i> 10 251-256
	Ofori-Adjei, D. et al. (1986) "Enantioselective analysis of chloroquine and desethylchloroquine after oral administration of racemic chloroquine," Therapeutic Drug Monitoring 8:457-461
	Ofori-Adjei, D. et al. (1986) "Protein binding of chloroquine enantiomers and desethyl- chloroquine," Br. J. Clin. Pharmac. 22:356-358
	Rosner, P.I. and Legros, J. (1967) "Hydroxychloroquine et resistance corticale a l'anoxie asphyxique," <i>Therapie</i> XXII:355-360
	Sharma, O.P. (1998) "Effectiveness of chloroquine and hydroxychloroquine in treating selected patients with sarcoidosis with neurological involvement," Archives of Neurology 55(9):1248-1254
	Shields, D.C. et al., (1999) "A putative mechanism of demyelination in multiple sclerosis by proteolytic enzyme, calpain," <i>Proc. Natl. Acad. Sci. USA</i> 96:11486-11491
	Tedeschi, M. (1983), "A case of acute psychosis due to Chloroquine," <i>Information Psychiatrique</i> 59(9):1191-1197 (Abstract)
	Webster, R.V. et al. (1991) "Antimalarial activity of optical isomers of quinacrine dihydrochloride against chloroquine-sensitive and -resistant <i>Plasmodium falciparum in vitro</i> ," <i>Biochem. Pharm.</i> 42:S225-S227

DATE CONSIDERED \*EXAMINER: initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449/PTO, based on PTO/SB/08A and 08B	Application Number	10/616,692
	Filing Date	July 9, 2003
INFORMATION DISCLOSURE	First Named Inventor	Nelson, Jodi
STATEMENT BY APPLICANT	Art Unit	1614
- 6)	Examiner Name	-Unassigned () . C. 1/1/C'
ನ∖	Attorney Docket Number	47-00B
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**U.S. PATENT DOCUMENTS** 

7	Examiner Initial*	Cite No.1	Document · Number (US-)	Publication Date (MM-DD-YYYY)	Name	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear (or entire document unless noted otherwise)

## **FOREIGN PATENT DOCUMENTS**

Examiner Initial*	Cite No.1	Foreign Patent Document Number (include WIPO country code)	Publication Date (MM-DD-YYYY)	Name	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear (or entire document unless noted otherwise)	T²

## **NON-PATENT LITERATURE DOCUMENTS**

Examiner Initial*	Cite No. <sup>1</sup>	REFERENCE Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
NA		Ben-Shachar, D. et al. (1993), "Iron, melanin and dopamine interaction: Relevance to Parkinson's disease," Progress in Neuro-Psychopharmacology and Biological Psychiatry, 17(1):139-150.	
		D'Ischia Marco et al. (1997) "Biosynthesis, structure and function of neuromelanin and its relation to Parkinson's disease: a critical update," Pigment Cell Research 110(6):370-376.	
		Garcia Ruiz, P.J., et al. (1992), "Cinnarizine-induced parkinsonism in primates," Clinical neuropharmacology 15(2):152-154 (Abstract)	<u>.</u>
	•	Garcia-Ruiz, P.J., et al. (1992) "Parkinsonism associated with calcium channel blockers: a prospective follow-up study," Clinical Neuropharmacology 15(1):19-26 (Abstract)	
		Geddes, J.F., et al. (1993), "Pathological overlap in cases of parkinsonism associated with neurofibrillary tangles. A study of recent cases of postencephalitic parkinsonism and comparison with progressive supranuclear palsy and Guamannaian parkinsonism-dementia complex," Brain, (Pt 1):281-302 (Abstract).	
	,	Hayase, Y, et al. (1997), "Influenza virus and neurological diseases," Psychiatry Clin. Neurosci. 41(4):181-4 (Abstract).	
V		Kuzuhara S., et al. (1989), "Parkinsonism, depression and akathisia induced by flunarizine, a calcium entry blockade-report of 31 cases," Rinsho shinkeigaku (Japan) 29 (6):681-686 (Abstract)	

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Sheet 2 of 2

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	Filing Date	July 9, 2003	
INFORMATION DISCLOSURE	First Named Inventor	Nelson, Jodi	
STATEMENT BY APPLICANT	Art Unit	1614	
(2)	Examiner Name	Unassigned	
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		Majno, G. et al. (1995), "Appoptosis, Oncosis, and Necrosis, An overview of Cell Death," American J. Pathology 146(1):3-16.	
		Negrotti, A. et al. (1992), "Calcium-entry blockers-induced parkinsonism: possible role of inherited susceptibility," Neurotoxicology 13(1):261-4 (Abstract)	
		Savenko, S.N., et al. (1975), "Histamine metabolism in patients with cerebral circulatory disorders together with hypertension and cerebral atherosclerosis," Zh Nevropatol Psikhiatr Im S S Korsakova 75(8):1162-7 (Abstract)	
		Takahashi, A., et al. (1993), "Drug-induced movement disorders," Nippon rinsho (JAPAN) 51(11):2929-34 (Abstract)	
	•	Tatton, N.A., et al. (Sept. 1998), "A fluorescent double-labeling method to detect and confirm apoptotic nuclei in Parkinson's disease," Annals of Neurology 44(3 Suppl 1):S142-148 (Abstract)	
W		Tatton, W.G., et al. (Sept., 1998), "Mitochondria in Neurodegenerative Apoptosis: an Opportunity for Therapy?" Annals of Neurology 44(3 Suppl. 1): S134-41 (Abstract)	

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 'Applicant's unique citation designation number (pptional).

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#### Sheet 1 of 2

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Substitute for form 1449/PTO, based on PTO/SB/08A and 08B	Application Number	10/616,692
	Filing Date	09/07/2003
INFORMATION DISCLOSURE	First Named Inventor	Nelson
STATEMENT BY APPLICANT	Art Unit	1614
STATEMENT BY APPLICANT	Examiner Name	Unassigned . C. JUNCS
٤\	Attorney Docket Number	47-00B

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**U.S. PATENT DOCUMENTS** 

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XX		1	5,496,836	03/05/1996	Di Rocco et al.	
[in]	/	2	5,352,688	10/04/1994	Kaminski	

## **FOREIGN PATENT DOCUMENTS**

Examiner Initial*	Cite No. <sup>1</sup>	Foreign Patent Document Number (include WIPO country code )	Publication Date (MM-DD-YYYY)	Name	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear (or entire document unless noted otherwise)	T²

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	3	ABIOSE, A.K., et al., Chloroquine-induced venodilation in human hand veins; Clinical Pharmacology & Therapeutics, June 1997, Vol. 61, No. 6, 677-683.	
M	4	ADLER, L.E., et al., Cimetidine Toxicity Manifested as Paranoia and Hallucinations; Am J Psychiatry, Sept. 1980, 137:9, 1112-1113.	
N)	5	BATEMAN, D. N., et al., Cimetidine induced postural and action tremor; <i>J Neurol Neurosurg Psychiatry</i> , Jan. 1981, 44(1):94.	
	6	AMABEOKU, G. J., Some behavioural effects of chloroquine in rats suggesting dopaminergic activation; <i>Indian J Med Res.</i> , Feb. 1994, 99:87-94.	
N.	7	BYRON, J. W., Mechanism for Histamine H₂-Receptor Induced Cell-Cycle Changes in the Bone Marrow Stem Cell; Agents & Actions, Jul. 1977, 7(2):209-13.	
	8	DONATELLI, P., et al., Stereoselective inhibition by chloroquine of histamine N-methyltransferase in the human liver and brain; <i>Eur J Clin Pharmacol.</i> , 1994, 47(4):345-9, abstract only.	
	9	ETTE, E.I., et al., Effect of ranitidine on chloroquine disposition; <i>Drug Intell Clin Pharm.</i> , Sept. 1987, 21(9):732-4.	
the	10	GARCIA-RUIZ, P.J., et al., Cinnarizine-induced parkinsonism in primates; Clinical Neuropharmacology, Apr 1992, 15(2):152-4, abstract only.	

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Application Number	10/616,692
Filing Date	09/07/2003
First Named Inventor	Nelson
Art Unit	1614
Examiner Name	Unassigned U.C. JeV ()
Attorney Docket Number	47-00B

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1			
	11	GARCIA-RUIZ, P.J., et al., Parkinsonism associated with calcium channel blockers: a	<del> </del>
1	• •	prospective follow-up study, <i>Clinical Neuropharmacology</i> , Feb. 1992, 15(1);19-26,	1
<b>X</b> ^\		abstract only.	
-h	12	HANDLER, C. E., et al., Extrapyramidal and cerebellar syndrome with	
	12	encephalopathy associated with cimetidine; Postgrad Med Journal, Aug. 1982,	
XX		58:527-528.	
	13	HARLE, D.G., et al., Structural features of potent inhibitors of rat kidney histamine N-	
		methyltransferase; <i>Biochem Pharmacol.</i> , Feb. 1988, 37(3):385-8, abstract only.	
A	- 14	HUTCHISON, T. A., et al., Comparative Dosage Table – Histamine H2 Receptors;	<del> </del>
	17	Drugdex® System, 2000.	
	15	KUSHNER, M. J., Chorea and Cimetidine; Annals of Internal Medicine, Jan. 1982,	
		96(1):126.	
(//	16	KUZUHARA, S., et al., Parkinsonism, depression and akathisia induced by	
\\\		flunarizine, a calcium entry blockade – report of 31 cases; Shinkeigaku (Japan), June	
<b>         </b>		1989, 29(6):681-6, abstract only.	
	- 17	LEHMANN, A. B., Reversible Chorea Due to Ranitidine and Cimetidine; The Lancet,	
CK	• •	July 1988, 2(8603):158.	
(1)	18	LOT, T. Y., The effects of chronic administration of chloroquine and quinacrine on the	
		response of normal and denervated smooth muscle to agonist drugs; Physiol Behav.,	
111		Aug. 1993, 54(2):345-9, abstract only.	
	19	McMAHON, T., Dyskinesia associated with amoxapine withdrawal and use of	
/ Mg/	_	carbamazepine and antihistamines; Psychosomatics, Feb. 1986, 27(2):145-148.	
T THE	20	NEGROTTI, A., et al., Calcium-entry blockers-induced parkinsonism: possible role of	
(A)		inherited susceptibility, Neurotoxicology, Spring 1992, 13(1):261-264, abstract only.	1
NX	21	POIRIER, J., et al., Debrisoquine Metabolism in Parkinsonian Patients Treated with	
		Antihistamine Drugs, The Lancet, Aug. 1987, p. 386.	
W	22	PORTER, J. B., et al., Intensive Hospital Monitoring Study of Intravenous Cimetidine,	
M		Arch Intern Med, Nov. 1986, 146:2237-9.	
	23	TAKAHASHI, A., et al., Drug-induced movement disorders; Nippon rinsho (Japan),	
\XX <sub>1</sub>		Nov. 1993, 51(11):2929-34, abstract only.	<u> </u>
INU	24	TOTTE, J., et al., Neurological Dysfunction Associated with Abnormal Levels of	
/MB		Cimetidine Metabolite, The Lancet, May 1981, 1(8228):1047.	L
JKX.	25	Micro Medex website, DRUGDEX® Drug Point, Drug Point® Summary,	
TAY:		FAMOTIDINE, printout Dec. 2005	
I My	26	Micro Medex website, CIME Adult Dosages, printout Dec. 2005	
WIX.	27	Micro Medex website, CQ Precautions, printout Dec. 2005	
W	28	Micro Medex website, CIME - Neurological AEs, printout Dec. 2005	
11			

	A			
Examiner Signature	house 6	The	Date Considered	

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03/05/1996

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Number (US-)

5,496,836

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**FOREIGN PATENT DOCUMENTS** 

Name

Di Rocco et al.

(or entire document unless noted otherwise)

7 pages

country code ) unless noted otherwise)	Examiner Initial*	Cite No. <sup>1</sup>	Foreign Patent Document - Number (include WIPO country code )	Publication Date (MM-DD-YYYY)	Name	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear (or entire document unless noted otherwise)	T²
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## **NON-PATENT LITERATURE DOCUMENTS**

Examiner Initial*	Cite No. <sup>1</sup>	REFERENCE Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²

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